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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,987	07/14/2003	Dennis O'Brien	10745.148	5971

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NYDEGGER & ASSOCIATES
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EXAMINER

HOUSTON, ELIZABETH

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 04/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 10/618,987	Applicant(s) O'BRIEN, DENNIS	
	Examiner Elizabeth Houston	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 24-31 is/are pending in the application.
- 4a) Of the above claim(s) 24-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5 and 8-12 is/are rejected.
- 7) ☒ Claim(s) 2-4, 6-7, 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 24-31 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: method for anchoring a device to a lesion in a vasculature can be performed with a materially different device, such as a stent with enlarged diameter at the ends.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 24-31 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, *the first flexible enclosure and the second flexible enclosure together with the flexible member forming an inflatable balloon as in claim 2* must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

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prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 5, 8-12 rejected under 35 U.S.C. 102(b) as being anticipated by O'Neill et al. (USPN 5,395,331). O'Neill teaches a system for anchoring a device to a lesion in the vasculature of a patient, which comprises a flexible member defining an axis and having an inner surface and an outer surface (Fig. 10, 302), and a fluid pump (15)

providing means for moving said member between a first configuration wherein said member is collapsed onto the axis and a second configuration wherein said member is made substantially rigid to embed said protuberances into the lesion and anchor the device to the lesion (Fig. 1, 15). The flexible member is formed with a plurality of bumps, which are made of the same material as the flexible member and are seamlessly interconnected to, and project outwardly from the member. (Fig. 10, 304; Col.11, line 34). In the embodiment in Figs 3 and 9, the ribs are asymmetrical in fashion (Col 11, line 19).

Response to Arguments

4. Applicant's arguments filed 03/11/2005 have been fully considered but they are not persuasive.

5. In the remarks in the first paragraph on page 11, applicant states that claim 1 was amended to overcome the rejection by O'Neill (USPN 5,395,331) to require that the protuberances extend radially outward from the outer surface of the flexible member. The definition of radially is "Radiating from or converging to a common center" as defined by The American Heritage® Dictionary of the English Language, Fourth Edition Copyright © 2000. In light of this definition, Figures 3 and 7 show protuberances that are extending radially from a common center, that center being the central axis of the balloon. Further, examiner respectfully disagrees that Figures 9-11 fail to show protuberances projecting radially. In Col 8, lines 21-27, O'Neill states that the proximal

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surface portions (58) extending outward from the proximal surface (46) at approximately a right angle to the proximal surface. Figures 9-11 clearly show that the balloon in its uninflated state is formed with a plurality of protuberances 304 and 404 projecting radially outward where the common center is the central axis.

6. Applicant also asserts that the instant invention includes a means for embedding the protuberances into the lesion and anchoring the device. According to The American Heritage® Dictionary of the English Language, Fourth Edition Copyright © 2000, the definition of embed is to enclose snugly or firmly. It does not assert the requirement of penetration as applicant implies in the remarks. Furthermore Roget's New Millennium™ Thesaurus, First Edition (v 1.1.1) Copyright © 2005, offers synonyms such as *press, set, and sink*. O'Neill teaches that the ribs are "frictionally engaged into the coronary sinus" as the balloon is inflated. Examiner asserts that as the balloon is further inflated, more pressure is exerted on the vessel. As the pressure on the vessel increases on the vessel, the protuberances are going to press up snugly against the vessel. Therefore O'Neill provides a means for embedding and thus anticipates the claims.

Allowable Subject Matter

7. Claims 2-4, 6-7, 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-Th 8:30-6:00 Alternate Fridays 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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GLENN K. DAWSON
PRIMARY EXAMINER